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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,903	03/30/2001	Daniel J. Balbierz	13724-844	7575

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EXAMINER
VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	09/823,903	BALBIERZ ET AL.	
	Examiner	Art Unit	
	Peter J Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9-12,14,22-25,28,29,31,32,34,42-50,52-74,79 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-7, 9-12, 14, 22-25, 28-29, 31-32, 34, 42-50,52-74, 79 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The instant action is **non-final** as new rejections are submitted below. These rejections include prior art that was unearthed in a recent update search performed by the Examiner.

Claims 2-4,8,13,15-21,26-27,30,33,35-41,51,75-78, and 81-82 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 5-7, 9-12, 14, 22-25, 28-29, 31-32, 34, 42-44, 49, 50, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron et al. ('609).

Gough et al. (Gough) discloses an apparatus for detecting and treating a tumor comprising:

Independent claims 1, 14, and 42(spectral profile limitation included in Benaron discussion below)

an *elongated delivery device* (figure 3; 10) including a lumen (14);

a *deployable sensor array* (24, col. 6:34-41 – can be "optical") including a plurality of resilient members (18 and 16) each having a tissue piercing (fig. 2c, 16) distal portion deployable from a compacted state with curvature (figure 3), the sensor array having a geometric configuration (figure 3) adapted to volumetrically sample tissue at a tissue site or multiple tissue sites to differentiate or identify tissue including tumor boundaries or boundaries between healthy and abnormal tissue (col. 4:63-67, **col. 6:23-34**) at the tissue site(s) during an energy delivery interval, as well as adapted to change direction of travel responsive to tissue applied forces;

electrodes (12,14,16, col. 4:42-44) coupled to (or comprising) the resilient members (18);

an *RF energy source* (20, col. 6:7-10);

logic resources (38, col. 10:40-46 and 50, col. 11: 5-8);

a handpiece (inherent) and an introducer or rigid advancement device (patented claim 36).

Dependent claims

Re: claim 5, Gough discloses a multiplexer (46) to measure and compare parameters at the numerous sensors (24) each providing measurements including temperature from different tissue volumes.

Re: claims 6-7, Gough discloses logic resources (38, col. 10:40-46 and 50, col. 11: 5-8) that in conjunction with the sensors (24) differentiate tissue types (col. 6:28-34).

Re: claims 9-11, Gough discloses a monitor /display device (36).

Re: claim 12, Gough discloses the ability through sensors and logic resources the ability to identify a clinical endpoint (col. 6:31-32, iii).

Re: claims 22-25, Gough discloses an optical fiber (col. 6:37-38) connected to a light source (inherent). Also see col. 6:14-18.

Re: claims 28-29, Gough discloses temperature sensors (24) that can detect tissue ablation volume (col. 6:28-33).

Re: claim 34, Gough discloses detection of cancerous and non-cancerous tissues ("tumor boundaries"; col. 4:63-67, **col. 6:23-34**).

Re: claim 43-44, and 49, Gough discloses a fiber optic emitter (24, col. 6:38). Optimal placement of the emitter as well as optimal frequency emittance would be obvious through routine experimentation.

Re: claim 50, Gough discloses an infusion port and cooling element (27, fig. 2(b).)

Re: claims 79 and 80, Gough discloses a handpiece (inherent) and advancement devices (introducers, patented claim 36, col.5: 5-10). Secondary advancement devices are also disclosed (16).

Gough neglects to disclose a spectral profile measurement.

Benaron et al. (Benaron) discloses an analogous tumor treatment method and apparatus comprising the use of a spectrophotometer (col. 8:42-53; col. 9:13-20), permitting spectral profile measurements of targeted tissue. The Applicant also uses a

spectrophotometer to undertake spectral profile measurements as submitted in the Specification page 16 line 13. Further, Benaron discloses logic resources (26, col. 9:16-20 and 147, col. 11:50-61)

Re: claim 31, Benaron discloses detection of structural and chemical cell changes during ablation.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron by including as a design expedient a spectrophotometer. The motivation to do so would be as posited by Benaron in col. 8:49-53, "to minimize risk of collateral damage or incomplete treatment, and to maximize success..."

2. Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron and further in view of Hoey et al. ('722).

Gough and Benaron neglect to disclose baseline measurements.

Hoey et al. (Hoey) discloses an analogous electrode tissue ablation method in which *baseline impedance measurements* (232) including reference signals are taken as depicted in figure 11. Further, Hoey discloses comparing (226,240) impedance measurements throughout the surgery and adjusting (228,246) energy delivery

parameters (RF power), accordingly, which further affect tissue ablation time and volume.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Hoey by including as a method step, that of obtaining and using impedance measurements to guide effective surgery. The motivation would be to "safeguard the patient and the apparatus," as submitted in Hoey col. 23:20-21.

3. Claims 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron and further in view of Ben-Haim et al. ('310).

Gough and Benaron do not disclose sensors that detect fluorescent markers.

Ben-Haim discloses an analogous ablation device with sensors (92) that detect fluorescent markers (col. 9:52-59).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Ben Haim by including sensors that detect contrast, flouresecence, cell activity, etc. The motivation would be to provide the surgeon further insight with regards to the surgical milieu such as cell activity and function during surgery, as well as to help differentiate different tissue types.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection. New art is presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
July 2, 2003

MICHAEL PEFFLEY
PRIMARY EXAMINER